

PATENT ABSTRACTS OF JAPAN

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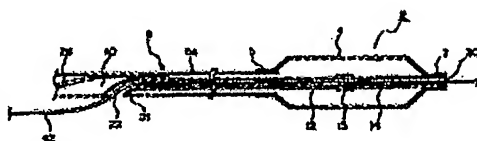
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(54) BALLOON FOR BALLOON CATHETER AND ITS MANUFACTURE

(57)Abstract:

PROBLEM TO BE SOLVED: To provide a thin balloon of high strength properly used for percutaneous transluminal coronary angioplasty(PTCA) by forming the balloon with a cross-linked tube made of a polyolefin resin, and determining a film thickness and the rupture strength of the balloon within ranges of specified values.

SOLUTION: A balloon for balloon catheter 2 is formed by the blow molding with a cross-linked tube made of a polyolefin resin, a film thickness of a balloon part 4 is 10-40 μm and its rupture strength is 800-2000 kgf/cm². Accordingly, the rupture strength of the balloon part 4 is remarkably high in comparison with a conventional balloon formed by the blow molding of a polyethylene resin, the balloon has high durability to high pressure for expanding the balloon, and the safety can be remarkably improved in the expansion of the vasoconstriction part when it is used, for example, for a PTCA balloon catheter. As the film thickness is remarkably thinned, a diameter can be reduced, which improves the medical treatment of the constriction of a peripheral arteria coronaria in comparison with a conventional one.



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CLAIMS

[Claim(s)]

[Claim 1]A balloon for balloon catheters, wherein it is the balloon fabricated by blow molding using a bridge construction tube which consists of polyolefin system resin, thickness of said balloon is 10-40 micrometers and breaking strength of said balloon is 800 - 2000 kgf/cm².

[Claim 2]Carry out electron beam bridge construction of the tube which consists of polyolefin system resin, and at temperature in which a gel content is lower than a process of preparing a bridge construction tube which is 0.2 to 0.8%, and the melting point of said polyolefin system resin, not less than 10 **. So that load of the primary blow pressure may be carried out to said bridge construction tube, it may rank second to it and effective draw magnification from this bridge construction tube to a balloon by carrying out load of the secondary blow pressure which is a pressure lower than said primary blow pressure to said bridge construction tube may be 500 to 1000%, A manufacturing method of a balloon for balloon catheters indicated to Claim 1 which has the process of carrying out blow molding and preparing a balloon part.

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DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[Field of the Invention]This invention closing in and a high intensity balloon about the balloon catheter which it has in detail, It is related with the suitable balloon catheter for an endermic blood vessel inner cap-like arterioplasty (Percutaneo second Transluminal Coronary Angioplasty and the following describe it as "PTCA".) use.

[0002]

[Description of the Prior Art]What is called a PTCA catheter dealt with and recovered simple with a balloon catheter is frequently used for the illness originating in strangulation of a blood vessel.

[0003]A PTCA catheter, for example in the treatment of the coronary arteries of the heart. A guiding catheter is first inserted to a coronary-arteries entrance, a guide wire is inserted exceeding a narrow segment, and a balloon catheter is pushed in to a narrow segment, and a narrow segment is extended by extending a balloon.

[0004]The PTCA catheter is also developing demand characteristics along with it, although expansion of the scope is achieved taking advantage of the advantage. For example, it is required that treatment of a peripheral coronary stenosis can be performed, that insertion in a crookedness blood vessel is easy, that it has strong dilatation pressure power, that vasodilatation can be done safely, etc. More specifically, it is called for using the PTCA catheter that treatment of a peripheral coronary stenosis can be performed rather than before. For that purpose, it is closing in more than before, and the balloon of high intensity is called for.

[0005]However, in the case of the polyethylene system resin (for example, JP,H8-196620,A etc.) mainly conventionally used as a charge of balloon material of a PTCA catheter, Generally it irradiates with an electron beam and the technique of aiming at improvement in improvement and bursting pressure of the extension characteristic as a balloon material, etc. is adopted by making a bridge construct until the gel fraction will be about 0.9%.

[0006]In this case, from about 0.9% of gel generating to the polyethylene system resin over which the bridge was constructed. In order that it might fall and the pressure which results in a burst might also decline, the intensity of a balloon had a limit in obtaining the balloon of high intensity by closing in, so that expansion of a balloon was only about 300% and the thickness became thin.

[0007]

[Problem(s) to be Solved by the Invention]The purpose of this invention aims at providing the suitable balloon for balloon catheters for closing in and a high intensity PTCA use. The purpose of this invention aims at providing the manufacturing method of said closing in and the high intensity balloon made of polyolefin system resin. The purpose of this invention aims at providing the balloon catheter which has said closing in and a high intensity balloon made of polyolefin system resin.

[0008]Then, as a result of inquiring wholeheartedly, this invention persons in the tube made of polyethylene resin. Give electron beam irradiation and a bridge is constructed so that the gel whose gel fraction is about 0.7% may generate, Then, the place which carried out blow molding of this bridge construction tube rather than the melting point of said polyethylene system resin on the 80 ** conditions which are quite low temperature, It finds out that the balloon whose disruptive strength draw magnification is 600% and is 1100 kgf/cm² is obtained, and came to complete this invention based on this knowledge.

[0009]

[Means for Solving the Problem]According to this invention, following (1), (2), and (3) are provided in this way.

(1) It is the balloon fabricated by blow molding using a bridge construction tube which consists of polyolefin system resin, A balloon for balloon catheters, wherein thickness of said balloon is 10-40 micrometers and breaking strength of said balloon is 800 - 2000 kgf/cm².

[0010](2) Carry out electron beam bridge construction of the tube which consists of polyolefin system resin, and

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at temperature in which a gel content is lower than a process of preparing a bridge construction tube which is 0.2 to 0.8%, and the melting point of said crystalline polyolefin system resin, not less than 10 **. So that load of the primary blow pressure may be carried out to said bridge construction tube, it may rank second to it and effective draw magnification from this bridge construction tube to a balloon by carrying out load of the secondary blow pressure which is a pressure lower than said primary blow pressure to said bridge construction tube may be 500 to 1000%. A manufacturing method of a balloon for balloon catheters indicated to the above (1) which has the process of carrying out blow molding and preparing a balloon part.

[0011](3) An outer tube in which at least one lumen for balloon extension is formed along with a longitudinal direction, So that a proximal end part of a balloon part may be joined to a distal end of said outer tube and space for extension sealed said lumen for balloon extension, a balloon part which an inside opens for free passage, and inside said balloon part may be formed, A distal end of a balloon part is joined to a distal end of an inner tube, and it has an inner tube which extends in shaft orientations inside said balloon part and a lumen for balloon extension of said outer tube, Said balloon part is the balloon fabricated by blow molding using a bridge construction tube which consists of polyolefin system resin, A balloon catheter, wherein thickness of said balloon is 10-40 micrometers and breaking strength of said balloon is 800 - 2000 kgf/cm².

[0012]In a manufacturing method of a balloon for balloon catheters of this invention, a tube which consists of polyolefin system resin is preferably irradiated with an electron beam of 10 - 20Mrad five to 40 Mrad, It is preferred that carry out electron beam bridge construction of said tube, and a gel content considers it as a bridge construction tube which is 0.2 to 0.7%. It is preferred to heat-treat the bridge construction tube concerned at at least 90 **.

[0013]In a manufacturing method of said balloon, when carrying out blow molding of said bridge construction tube, A thing which carry out 15-25 kgf/cm² load of the primary blow pressure to a metallic mold, and opens a metallic mold and for which load of the secondary blow pressure of 5 - 8 kgf/cm² is carried out, and a balloon is created 1 second ago at least is preferred.

[0014]As for thickness of a balloon for balloon catheters which consists of polyolefin system resin, in this invention, it is preferred that it is 25-35 micrometers.

[0015]As for a balloon for balloon catheters which consists of polyolefin system resin, in this invention, it is preferred that effective draw magnification from said bridge construction tube to a balloon is 500 to 700%. It is preferred that breaking strength of said balloon is 1000 - 2000 kgf/cm².

[0016]

[Function]The balloon for balloon catheters of this invention is compared with the balloon usually produced by carrying out blow molding of the polyethylene resin, When the high pressure force for balloon extension can be borne, for example, it is used as a PTCA balloon catheter from the disruptive strength of a balloon being very high, the safety at the time of extending a vasoconstriction portion is extremely excellent.

[0017]Since the balloon for balloon catheters of this invention can make the thickness very thin, when using it as a balloon of a PTCA catheter, it can narrow-diameter-ize a PTCA catheter and the treatment of a peripheral coronary stenosis of it is attained rather than before, for example.

[0018]

[Embodiment of the Invention]The balloon for balloon catheters of this invention is prepared using polyolefin system resin. The olefin of the carbon numbers 2-40 is used for said polyolefin system resin as a monomer, it manufactures it by a polymerization reaction, and the density (JIS K-7112), Usually, it is 0.950 g/cm³ or less and 0.850-0.940 g/cm³ is 0.880-0.930 g/cm³ more preferably. Since transparency will fall if too large [if density is too low, it will become easy to produce inconvenience, such as blocking depended with solid ones on the surface of a balloon, and], it is not desirable.

[0019]As a monomer of the olefin for obtaining polyolefin system resin by a polymerization reaction, Ethylene, propylene, 1-butene, 1-pentene, 1-hexene, 1-octene, 1-heptene, 4-methyl-1-pentene, a 4-methyl-1-hexene, 4,4-dimethyl-1-pentene, etc. are mentioned. These monomers are independent, respectively or can be used combining two or more sorts.

[0020]As polyolefin system resin, from a viewpoint of the various characteristics as a balloon, polyethylene, ethylene, and an alpha olefin copolymer are preferred, and especially ethylene and an alpha olefin copolymer are preferred. Ethylene and an alpha olefin copolymer can be obtained by carrying out copolymerization of ethylene and the alpha olefin using a metallocene catalyst. As comonomer, it is preferred to use alpha olefin with 4-40 carbon atoms.

[0021]As said alpha olefin, 1-butene, 1-pentene, 1-hexene, 1-octene, 1-heptene, 4-methyl-1-pentene, a 4-methyl-1-hexene, 4,4-dimethyl-1-pentene, etc. are mentioned, for example. Also in these, the alpha olefin of 4-12 has the preferred number of carbon atoms, and the alpha olefin of 4-10 has the more preferred number of

the 2nd blow pressure — 3 – 10 kgf/cm² — it is 5 – 8 kgf/cm² preferably.

[0032]It is fabricated by the shape which has 7 f of portions for joining to the balloon body portion 7e and a balloon catheter by the blow molding mentioned above as a balloon is shown, for example in drawing 3 (B).

[0033]The outer diameter of the balloon fabricated by blow molding measures an outer diameter when the pressure of 1atm or 6atm is applied with a laser outer diameter measuring instrument. The thickness of a balloon is measured with a micro gauge.

[0034]The effective draw magnification (a bridge construction tube cross-section area / balloon cross-section area) from a bridge construction tube to the balloon of the balloon fabricated by blow molding needs to be 500 to 1000% preferably 400 to 1500%. When too large, since the disruptive strength of a balloon falls extremely, effective draw magnification is not preferred. In this invention, said extrusion tube is irradiated with an electron beam on condition of 5 – 40Mrad, and the bridge construction tube made from polyethylene is formed. Therefore, in said effective draw magnification, it is 400 to 1500%, and it is attained for the breaking strength of said balloon 800 – 2000 kgf/cm² and that it is 1000 – 1800 kgf/cm² preferably.

[0035]In this invention, 5–40 micrometers of thickness of the balloon fabricated by said blow molding are 25–35 micrometers preferably.

[0036]In underwater [37 **], the breaking strength of a balloon pressurizes 15 psi of balloons, is held for 15 seconds, then carries out additional pressure of the 15 more psi, holds it for 15 seconds, and it measures a pressure when it explodes as breaking strength repeatedly until a balloon explodes this step.

[0037]The disruptive strength of the balloon which carried out blow molding by the method mentioned above is shown in Table 1. The dose of the electron beam was prepared by 40Mrad and 60Mrad, and the disruptive strength of the balloon which carried out blow molding using what has a gel content in the same grade as the conventional bridge construction tube was shown in Table 1 as a comparative example. The result of Table 1 shows that as for the balloon for balloon catheters of this invention the thickness of a balloon has thin effective draw magnification in not less than 500%, and disruptive strength is increasing substantially.

[0038]

[Table 1]

	実 施 例					比較例	
	1	2	3	4	5	1	2
電子線照射量MR.	20	20	20	20	20	40	60
ゲル含量%	0.7	0.7	0.7	0.7	0.7	0.9	1.0
有効延伸倍率%	530	550	580	610	540	310	280
膜厚 μm	23	24	29	17	25	48	66
破壊応力kgf/cm ²	1311	1213	1135	1614	1161	870	690

[0039]Next, the embodiment of the balloon catheter which uses the balloon for balloon catheters of this invention is described based on Drawings. The entire configuration figure of the balloon catheter which requires drawing 1 (A) for one embodiment of this invention, The sectional view which meets the IB-IB line which shows drawing 1 (A) drawing 1 (B), the sectional view which meets the IC-IC line which shows drawing 1 (A) drawing 1 (C), the sectional view which meets the ID-ID line which shows drawing 1 (A) drawing 1 (D), and drawing 1 (E) show the sectional view which meets the IE-IE line shown in drawing 1 (A). Drawing 2 shows important section drawing of longitudinal section of the balloon catheter shown in drawing 1 (A).

[0040]The balloon catheter 2 concerning this embodiment shown in drawing 1 is used for methods, such as an extended way of blood vessels, such as percutaneous transluminal coronary angioplasty (PTCA) and the limbs, an extended way of a top ureter, and a renal vasodilatation way, for example, and it is used in order to extend the narrow segment formed in a blood vessel or the other abdominal cavities. The following explanation explains as an example the case where the balloon catheter 2 of this embodiment is used for PTCA.

[0041]The balloon catheter 2 for extension of this embodiment is the so-called balloon catheter of a monorail method.

It has the balloon part 4, the outer tube 6 as a catheter tube, and the connector 8.

The outer tube 6 consists of the comparatively supple 1st outer tube member 6a and the 2nd outer tube member 6b with comparatively high rigidity joined to the 1st outer tube member 6a concerned by the joined part

9.

[0042] Penetrate the tube wall located in the middle of the longitudinal direction of the 1st outer tube member 6a, and the proximal edge opening of an inner tube carries out the opening of this embodiment outside, and The proximal edge opening of an inner tube, By adopting the structure where thermal melting arrival of the tube wall of the 1st outer tube member 6a has been carried out airtightly, only the distal end of a balloon catheter serves as the so-called catheter tube structure of coaxial structure.

[0043] As shown in drawing 1 (C), in this embodiment the cross section contour shape of the 2nd outer tube member 6b, The maximum sectional width x_m of the catheter tube of an X axial direction vertical to a Y-axis in the section of the outer tube member 6 which has elliptical [long and slender] in Y shaft orientations, a ratio (x_m/y_m) with the maximum sectional width y_m of Y shaft orientations is in the range of 0.8-0.1 — the 3rd of section semicircular shapes — lumen 24 and a round cross section — the 4th lumen, along said Y shaft orientations, 26 dissociates and is formed.

[0044] The 3rd lumen, the cross sectional area of the semicircular shapes of 24 should just be cross sectional area sufficient in order that the pressure fluid for balloon extension may circulate, and although it is not limited in particular, it is 0.08-0.20- mm^2 preferably. The 4th lumen, the circular cross sectional area of 26 should just be area sufficient since the reinforcing rod 28 is inserted in an inside, and although it is not limited in particular, it is 0.1-0.2- mm^2 preferably [it is desirable and] to 0.05-0.5- mm^2 and a pan.

[0045] As for the maximum sectional width y_m of Y shaft orientations, in this embodiment, about 0.6-1.2 mm is preferred in the section of the 2nd outer tube member 6b. Since the distal end of the 2nd outer tube member 6b is joined to the proximal edge of the 1st outer tube member 6a of a round cross section, the lateral cross sectional shape of the joined part 9 neighborhood, In order to make it in agreement with circular section shape with the 1st outer tube member 6a, it is considered as sectional shape which changes from an irregular shape cross to a circular section gradually towards the joined part 9.

[0046] the 3rd formed along with the longitudinal direction of this 2nd outer tube member 6b — lumen 24 — the 1st outer tube member 6a — the 1st lumen is open for free passage with 10, it lets these pass, and a fluid is taken in and out of the space for extension of the balloon part 4. It is a lumen for 26 to insert [of the 2nd outer tube 6b] the 4th lumen of the reinforcing rod 28.

the 1st outer tube member 6a — although 10 [lumen / 1st] is open for free passage, the proximal edge of this lumen 26 is closed in the portion of the connector 8, and receipts and payments of a fluid are not performed. The proximal end part of the 2nd outer tube member 6c is connected with the connector 8, and the port of the 2nd outer tube 6b which is open for free passage to 24 the 3rd lumen is formed in it. A port is a portion which goes a pressure fluid in and out.

The 4th lumen is open for free passage to 26.

[0047] the reinforcing rod 28 shown in drawing 1 (B), (C), and (F) — the 2nd outer tube member 6b — the overall length was covered and it was inserted in the inside of 26, and the distal end overcame the joined part 9 with the 1st outer tube member 6a, and the 4th lumen is sticking out of it in 1st lumen 10 of the 1st outer tube member 6a. The proximal end part of the reinforcing rod 28 is a round cross section.

It becomes thin to tapered shape towards the middle to the distal end side, and further, the sectional shape is changing gradually in the distal end so that it may grow into section flat plate shape.

As shown in drawing 1 (D) and drawing 2, the distal end of the section plate-like reinforcing rod 28 is the position which also overcame slightly (preferably about 1-10 cm) the proximal edge opening 22 of the inner tube 12, and is joined by thermal melting arrival, adhesion, or other means to the wall of the 1st outer tube member 6a.

[0048] Although the maximum outer diameter of the reinforcing rod 28 is determined possible [the 4th lumen of the insertion to the inside of 26] for the 2nd outer tube member 6b and is not limited in particular, it is 0.3-0.6 mm preferably.

[0049] The balloon part 4 shown in drawing 1 and drawing 2 comprises a tubed membrane by which the diameter of both ends was reduced, and 10-40 micrometers of the thickness is 15-35 micrometers preferably. As long as the balloon part 4 is cylindrical, it may not be limited in particular but a cylinder or the shape of a multiple cartridge may have as it. The outer diameter of the balloon part 4 at the time of extension is usually 3-7 mm preferably about 1.5-10.0 mm. Although the shaft-orientations length in particular of the balloon part 4 is not limited, it is 20-40 mm preferably 15-50 mm. The balloon part 4 before extending is folded up around the inner tube 12, and is twisted, and the outer diameter is small as much as possible.

[0050] having joined the proximal end part 5 of the balloon part 4 to the distal end periphery of the 1st outer tube member 6a by thermal melting arrival, adhesion, or other means, as shown in drawing 2 — the 1st outer tube

member 6a -- 10 [lumen / 1st] is open for free passage with the space for internal extension of the balloon part 4. The distal end 7 of the balloon part 4 is joined by thermal melting arrival, adhesion, or other means to the distal end periphery of the inner tube 14, and the space for internal extension of the balloon part 4 is sealed to the exterior except 1st lumen 10. It is a passage for [of the 1st outer tube member 6a] 10 sending the 1st lumen of a fluid into the internal growth space of the balloon part 4, and making the balloon part 4 extend, or sampling a fluid from the growth space of the balloon part 4, and shrinking the balloon part 4.

[0051]As shown in drawing 2, as for the growth space [of the balloon part 4], and distal end side of the 1st outer tube member 6a, the 1st lumen of the inner tube 12 is extended to shaft orientations in the shape of the same axle in the inside of 10, and has the so-called catheter tube structure of coaxial structure. The periphery of the inner tube 12 located in the inside of the balloon part 4 is equipped with the imaging ring 15, and when inserting the balloon catheter 2 in the living body, imaging is possible about the position of the imaging ring 15 through a living body's exterior to X-rays etc. Metal, such as gold, platinum, and tungsten, is illustrated as a material of the imaging ring 15.

[0052]14 [lumen / 2nd] is formed in the inside of the inner tube 12, and the opening of the distal end opening 20 is carried out to it in the distal end 7 of the balloon part 4. The proximal edge opening 22 of the inner tube 12 penetrates the breakthrough 21 of a tube wall located in the middle of the longitudinal direction of the 1st outer tube member 6a, and is carrying out the opening outside. The periphery of the proximal edge opening 22 of the inner tube 12 and the periphery of the breakthrough 21 of the tube wall of the 1st outer tube member 6a are airtightly joined by the thermal melting arrival method mentioned later. Although the shape in particular of the proximal edge opening 22 of the inner tube 12 is not limited but can take various shape, such as circular and an ellipse form, as shown in drawing 5, it is elliptical [which cut the open end of the inner tube 12 aslant] in this embodiment. The 2nd lumen turns into a lumen for guidewire insertion which the guidewire 42 shown in drawing 2 for 14 to guide [of the inner tube 12] the balloon catheter 2 into the abdominal cavity inserts in.

[0053]Although the inner tube 12 can be constituted from soft synthetic resin of the same material as the 1st outer tube member 6a, a hard synthetic resin may constitute it from the 1st outer tube member 6a. As for the position, as for, the proximal edge opening 22 of the inner tube 12 carries out an opening to the outside of the 1st outer tube member 6a, it is preferred that it is a position of the distal end of the 1st outer tube member 6a to the length L1, and the length L1 is 200-300 mm still more preferably 150-350 mm preferably.

[0054]Although the outer diameter in particular of the 1st outer tube member 6a is not limited, it is 0.5-1 mm still more preferably 0.5-5 mm preferably. Although the thickness in particular of the 1st outer tube member 6a is not limited, it is 0.1-0.2 mm still more preferably 0.05-0.5 mm preferably.

[0055]Although the outer diameter of the inner tube 12 is determined that a crevice is formed and is not limited in particular between the 1st outer tube members 6a, it is 0.3-0.8 mm still more preferably 0.3-3 mm preferably. Especially if the inside diameter of the inner tube 12 is a path which can insert in the guidewire 42, it will not be limited, for example, it is 0.25-0.6 mm preferably 0.15-1.0 mm.

[0056]According to this embodiment, in order to reinforce the intensity of the 1st outer tube member 6a by the side of a proximal edge from the opening 22 neighborhood, as shown in drawing 2, the reinforcing rod 28 may be arranged from the opening 22 neighborhood inside the 1st outer tube member 6a by the side of a proximal edge. The proximal end part of this reinforcing rod 28 is a round cross section.

It becomes thin to tapered shape towards the middle to the distal end side, and further, the sectional shape is changing gradually in the distal end so that it may grow into section flat plate shape.

As shown in drawing 2, the distal end of the section plate-like reinforcing rod 28 is the position which overcame slightly (preferably about 1-10 cm) the proximal edge opening 22 of the inner tube 12, and is joined by thermal melting arrival, adhesion, or other means to the wall of the 1st outer tube member 6a.

[0057]The reinforcing rod 28 consists of synthetic resins, such as metallic materials, such as stainless steel, copper, a copper alloy, titanium, and a titanium alloy, or polyimide, polyamide, and polyethylene terephthalate. Although the maximum outer diameter of the reinforcing rod 28 is determined that it will not close the lumen 10 of the 1st outer tube member 6a and is not limited in particular, it is 0.3-0.6 mm preferably.

[0058]Although the 1st outer tube member 6a may comprise the same material as the balloon part 4, for example, it is preferred to comprise material which has flexibility. For example, polyethylene, polyethylene terephthalate, polypropylene, Ethylene propylene rubber, an ethylene-vinylacetate copolymer, polyvinyl chloride (PVC), The constructed type ethylene-vinylacetate copolymer of a bridge, polyurethane, polyamide, A polyamide elastomer, polyimide, a polyimide elastomer, polytetrafluoroethylene resin, Tetrafluoroethylene hexafluoride propylene copolymerization resin, tetrafluoroethylene perfluoroalkyl vinyl ether copolymerization resin, Ethylene chloride trifluoride resin, tetrafluoroethylene ethylene copolymerization resin, polyvinylidene fluoride resin, polyvinyl fluoride, silicone rubber, crude rubber, etc. are mentioned. Especially, polyethylene, polyamide, and polyimide are preferred. That whose JIS hardness is about 50A-90A can be used for the hardness of the 1st

outer tube member 6a concerned.

[0059]The 2nd outer tube member 6b comprises the same material as said 1st outer tube member. That whose JIS hardness is about 50D-75D can be used for the hardness of the 2nd outer tube member 6b concerned.

[0060]It is preferred to have covered with this embodiment the covering material which comprises the hydrophilic polymer material which has lubricity in the periphery of the outer tube 6 which comprises the 1st outer tube member 6a and the 2nd outer tube member made of a fluoro-resin by a damp or wet condition.

[0061]

[Effect of the Invention]In this way, according to this invention, the thickness of a balloon is thin and the balloon for balloon catheters in which the disruptive strength improved substantially is provided. The balloon for balloon catheters of this invention is compared with the balloon usually produced by carrying out blow molding near the melting point of crystalline polyethylene resin (110 **), Since the thickness of the balloon was thin and the disruptive strength was high, when a balloon catheter can be narrow-diameter-ized, and the high pressure force for balloon extension can be borne further, for example, it is used as a PTCA balloon catheter, the safety at the time of extending a vasoconstriction portion is extremely excellent.

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TECHNICAL FIELD

[Field of the Invention]This invention closing in and a high intensity balloon about the balloon catheter which it has in detail, It is related with the suitable balloon catheter for an endermic blood vessel inner cap-like arterioplasty (Percutaneo second Transluminal Coronary Angioplasty and the following describe it as "PTCA".) use.

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PRIOR ART

[Description of the Prior Art]What is called a PTCA catheter dealt with and recovered simple with a balloon catheter is frequently used for the illness originating in strangulation of a blood vessel.

[0003]A PTCA catheter, for example in the treatment of the coronary arteries of the heart. A guiding catheter is first inserted to a coronary-arteries entrance, a guide wire is inserted exceeding a narrow segment, and a balloon catheter is pushed in to a narrow segment, and a narrow segment is extended by extending a balloon.

[0004]The PTCA catheter is also developing demand characteristics along with it, although expansion of the scope is achieved taking advantage of the advantage. For example, it is required that treatment of a peripheral coronary stenosis can be performed, that insertion in a crookedness blood vessel is easy, that it has strong dilatation pressure power, that vasodilatation can be done safely, etc. More specifically, it is called for using the PTCA catheter that treatment of a peripheral coronary stenosis can be performed rather than before. For that purpose, it is closing in more than before, and the balloon of high intensity is called for.

[0005]However, in the case of the polyethylene system resin (for example, JP,H8-196620,A etc.) mainly conventionally used as a charge of balloon material of a PTCA catheter, Generally it irradiates with an electron beam and the technique of aiming at improvement in improvement and bursting pressure of the extension characteristic as a balloon material, etc. is adopted by making a bridge construct until the gel fraction will be about 0.9%.

[0006]In this case, from about 0.9% of gel generating to the polyethylene system resin over which the bridge was constructed. In order that it might fall and the pressure which results in a burst might also decline, the intensity of a balloon had a limit in obtaining the balloon of high intensity by closing in, so that expansion of a balloon was only about 300% and the thickness became thin.

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EFFECT OF THE INVENTION

[Effect of the Invention]In this way, according to this invention, the thickness of a balloon is thin and the balloon for balloon catheters in which the disruptive strength improved substantially is provided. The balloon for balloon catheters of this invention is compared with the balloon usually produced by carrying out blow molding near the melting point of crystalline polyethylene resin (110 **). Since the thickness of the balloon was thin and the disruptive strength was high, when a balloon catheter can be narrow-diameter-ized, and the high pressure force for balloon extension can be borne further, for example, it is used as a PTCA balloon catheter, the safety at the time of extending a vasoconstriction portion is extremely excellent.

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TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention]The purpose of this invention aims at providing the suitable balloon for balloon catheters for closing in and a high intensity PTCA use. The purpose of this invention aims at providing the manufacturing method of said closing in and the high intensity balloon made of polyolefin system resin. The purpose of this invention aims at providing the balloon catheter which has said closing in and a high intensity balloon made of polyolefin system resin.

[0008]Then, as a result of inquiring wholeheartedly, this invention persons in the tube made of polyethylene resin. Give electron beam irradiation and a bridge is constructed so that the gel whose gel fraction is about 0.7% may generate, Then, the place which carried out blow molding of this bridge construction tube rather than the melting point of said polyethylene system resin on the 80 ** conditions which are quite low temperature, It finds out that the balloon whose disruptive strength draw magnification is 600% and is 1100 kgf/cm² is obtained, and came to complete this invention based on this knowledge.

[Translation done.]

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MEANS

[Means for Solving the Problem]According to this invention, following (1), (2), and (3) are provided in this way.

(1) It is the balloon fabricated by blow molding using a bridge construction tube which consists of polyolefin system resin, A balloon for balloon catheters, wherein thickness of said balloon is 10-40 micrometers and breaking strength of said balloon is 800 - 2000 kgf/cm².

[0010](2) Carry out electron beam bridge construction of the tube which consists of polyolefin system resin, and at temperature in which a gel content is lower than a process of preparing a bridge construction tube which is 0.2 to 0.8%, and the melting point of said crystalline polyolefin system resin, not less than 10 **. So that load of the primary blow pressure may be carried out to said bridge construction tube, it may rank second to it and effective draw magnification from this bridge construction tube to a balloon by carrying out load of the secondary blow pressure which is a pressure lower than said primary blow pressure to said bridge construction tube may be 500 to 1000%, A manufacturing method of a balloon for balloon catheters indicated to the above (1) which has the process of carrying out blow molding and preparing a balloon part.

[0011](3) An outer tube in which at least one lumen for balloon extension is formed along with a longitudinal direction, So that a proximal end part of a balloon part may be joined to a distal end of said outer tube and space for extension sealed said lumen for balloon extension, a balloon part which an inside opens for free passage, and inside said balloon part may be formed, A distal end of a balloon part is joined to a distal end of an inner tube, and it has an inner tube which extends in shaft orientations inside said balloon part and a lumen for balloon extension of said outer tube, Said balloon part is the balloon fabricated by blow molding using a bridge construction tube which consists of polyolefin system resin, A balloon catheter, wherein thickness of said balloon is 10-40 micrometers and breaking strength of said balloon is 800 - 2000 kgf/cm².

[0012]In a manufacturing method of a balloon for balloon catheters of this invention, a tube which consists of polyolefin system resin is preferably irradiated with an electron beam of 10 - 20Mrad five to 40 Mrad, It is preferred that carry out electron beam bridge construction of said tube, and a gel content considers it as a bridge construction tube which is 0.2 to 0.7%. It is preferred to heat-treat the bridge construction tube concerned at at least 90 **.

[0013]In a manufacturing method of said balloon, when carrying out blow molding of said bridge construction tube, A thing which carry out 15-25 kgf/cm² load of the primary blow pressure to a metallic mold, and opens a metallic mold and for which load of the secondary blow pressure of 5 - 8 kgf/cm² is carried out, and a balloon is created 1 second ago at least is preferred.

[0014]As for thickness of a balloon for balloon catheters which consists of polyolefin system resin, in this invention, it is preferred that it is 25-35 micrometers.

[0015]As for a balloon for balloon catheters which consists of polyolefin system resin, in this invention, it is preferred that effective draw magnification from said bridge construction tube to a balloon is 500 to 700%. It is preferred that breaking strength of said balloon is 1000 - 2000 kgf/cm².

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OPERATION

[Function]The balloon for balloon catheters of this invention is compared with the balloon usually produced by carrying out blow molding of the polyethylene resin. When the high pressure force for balloon extension can be borne, for example, it is used as a PTCA balloon catheter from the disruptive strength of a balloon being very high, the safety at the time of extending a vasoconstriction portion is extremely excellent.

[0017]Since the balloon for balloon catheters of this invention can make the thickness very thin, when using it as a balloon of a PTCA catheter, it can narrow-diameter-ize a PTCA catheter and the treatment of a peripheral coronary stenosis of it is attained rather than before, for example.

[0018]

[Embodiment of the Invention]The balloon for balloon catheters of this invention is prepared using polyolefin system resin. The olefin of the carbon numbers 2-40 is used for said polyolefin system resin as a monomer, it manufactures it by a polymerization reaction, and the density (JIS K-7112) is usually 0.950 g/cm³ or less. 0.850-0.940 g/cm³ is 0.880-0.930 g/cm³ more preferably.

Since transparency will fall if too large [if density is too low, it will become easy to produce inconvenience, such as blocking depended with solid one on the surface of a balloon, and], it is not desirable.

[0019]As a monomer of the olefin for obtaining polyolefin system resin by a polymerization reaction, Ethylene, propylene, 1-butene, 1-pentene, 1-hexene, 1-octene, 1-heptene, 4-methyl-1-pentene, a 4-methyl-1-hexene, 4,4-dimethyl-1-pentene, etc. are mentioned. These monomers are independent, respectively or can be used combining two or more sorts.

[0020]As polyolefin system resin, from a viewpoint of the various characteristics as a balloon, polyethylene, ethylene, and an alpha olefin copolymer are preferred, and especially ethylene and an alpha olefin copolymer are preferred. Ethylene and an alpha olefin copolymer can be obtained by carrying out copolymerization of ethylene and the alpha olefin using a metallocene catalyst. As comonomer, it is preferred to use alpha olefin with 4-40 carbon atoms.

[0021]As said alpha olefin, 1-butene, 1-pentene, 1-hexene, 1-octene, 1-heptene, 4-methyl-1-pentene, a 4-methyl-1-hexene, 4,4-dimethyl-1-pentene, etc. are mentioned, for example. Also in these, the alpha olefin of 4-12 has the preferred number of carbon atoms, and the alpha olefin of 4-10 has the more preferred number of carbon atoms. The copolymerization ratio of alpha olefin is 2 to 50 % of the weight usually 10 to 30 % of the weight more preferably five to 40% of the weight.

[0022]As an example of said polyolefin system resin, polyethylene resin, polypropylene resin, ethylene-propylene copolymerization resin, copolymerization resin of ethylene and other alpha olefins, etc. are mentioned, for example. Polyethylene resin is especially preferred and it is preferred to use low density polyethylene, straight-chain-shape low density polyethylene, high density polyethylene, etc.

[0023]the melt flow rate (MFR;JIS K-7210) of said polyolefin system resin -- usually -- 0.1-30.0g/10 minutes -- desirable -- 1.0-20.0g/10 minutes -- more -- desirable -- 1.0-15.0g/10 minutes most preferably for 10 minutes. If it is difficult to obtain sufficient intensity if MFR is too small and it is too large, moldability will fall.

[0024]In this invention, various additive agents can be blended with polyolefin system resin within limits which do not spoil the purpose of this invention. As an additive agent, an antioxidant, an ultraviolet ray absorbent, a spray for preventing static electricity, fire retardant, a metal deactivator, paints, a color, a nucleus agent, etc. can be added in some numbers if needed, for example. In this case, although based on the character to demand, 20 or less weight sections of additions are usually five or less weight sections preferably to polyolefin-system-resin 100 weight section.

[0025]The manufacturing method of the balloon for balloon catheters of this invention is explained. First, the former tube for blow molding of the size designed beforehand is fabricated using crystalline polyolefin system resin. Being able to perform shaping, for example by an extrusion-molding method, the die temperature at the

time of extrusion is 200–300 **, for example. From a die, the extrusion tube just behind the regurgitation passes the inside of a tank (20–30 **), for example, and is cooled.

[0026]Next, said extrusion tube is irradiated with an electron beam, and the bridge construction tube made of polyolefin system resin (it is hereafter described as "parison".) is formed. The dose of an electron beam is 10 – 20Mrad preferably five to 40 Mrad, for example. Then, as for said bridge construction tube, heat treatment is performed, for example at about 90–110 ** for 30 minutes – several hours. The shaping strain by extrusion molding is canceled by this heat treatment process.

[0027]As for the gel fraction of the tube over which the bridge was constructed by said electron beam irradiation, it is preferred preferably to consider it as about 0.2 to 0.7% 0.8% or less. A gel fraction can be measured as insoluble content in the inside of the xylene which the bridge construction sample heated. After specifically heating a 0.1–g bridge construction sample for 6 hours in 100 ml of xylene heated at 120 **, extractives are filtered, the dry weight of the left-behind bridge construction sample is measured, and the rate over the bridge construction sample before processing is computed.

[0028]For example, size enlargement of the parison prepared through the above-mentioned process is carried out to the shape of a balloon by blow molding through the following process. First, the upper and lower sides of parison are fixed like drawing 3 (A). It closes so that a pressure may not leak thoroughly, and it is made not to crush a lumen by a top zipper, so that blow pressure may be applied to a lower zipper.

[0029]Next, blow molding of said parison is carried out at a temperature lower than the melting point of crystalline polyolefin system resin of parison material. Said not less than at least 10 ** of temperature is the temperature by the side of not less than 30 ** low temperature preferably from the melting point of crystalline polyolefin form resin, for example.

About 30–60 ** is a range by the side of low temperature still more preferably.

In a hot case, in blow molding, said temperature becomes easy too much, but the disruptive strength of a balloon falls. On the other hand, in order to carry out size enlargement of the balloon at low temperature too much, very high voltage blow pressure is needed, and it is not desirable. Since contraction breaks out extremely, the balloon which carried out blow molding by the low temperature side is not preferred.

[0030]Specifically, blow molding is based on the following process. For example beforehand, at around 50–90 **, preferably, the range of the parison which had the upper and lower sides fixed is 75–85 **, and for 30180 minutes, after being preferably heated for 100 to 150 minutes, it is extended by the sliding direction about 150 to 200% at this embodiment. Next, at the same time as parison was extended, it is closed so that the metallic mold (it has heated to the same extent as parison) comparatively carried out two from both sides may sandwich parison, then load of the 1st blow pressure is carried out, and for [20 to 40 seconds] grade maintenance is preferably carried out for 10 to 60 seconds. Next, even if there is little 1st blow pressure, it is preferably held for 0.5 to 3 seconds 1/2 or less with 1/3 or less blow pressure (it is hereafter described as "the 2nd blow pressure".), and a metallic mold can open after that.

[0031]Although the gas in particular introduced into parison is not limited, nitrogen gas etc. can be used for it, for example. the 1st blow pressure for expanding parison — 10 – 30 kgf/cm² — it is 15 – 25 kgf/cm² preferably. the 2nd blow pressure — 3 – 10 kgf/cm² — it is 5 – 8 kgf/cm² preferably.

[0032]It is fabricated by the shape which has 7 f of portions for joining to the balloon body portion 7e and a balloon catheter by the blow molding mentioned above as a balloon is shown, for example in drawing 3 (B).

[0033]The outer diameter of the balloon fabricated by blow molding measures an outer diameter when the pressure of 1atm or 6atm is applied with a laser outer diameter measuring instrument. The thickness of a balloon is measured with a micro gauge.

[0034]The effective draw magnification (a bridge construction tube cross-section area / balloon cross-section area) from a bridge construction tube to the balloon of the balloon fabricated by blow molding needs to be 500 to 1000% preferably 400 to 1500%. When too large, since the disruptive strength of a balloon falls extremely, effective draw magnification is not preferred. In this invention, said extrusion tube is irradiated with an electron beam on condition of 5 – 40Mrad, and the bridge construction tube made from polyethylene is formed. Therefore, in said effective draw magnification, it is 400 to 1500%, and it is attained for the breaking strength of said balloon 800 – 2000 kgf/cm² and that it is 1000 – 1800 kgf/cm² preferably.

[0035]In this invention, 5–40 micrometers of thickness of the balloon fabricated by said blow molding are 25–35 micrometers preferably.

[0036]In underwater [37 **], the breaking strength of a balloon pressurizes 15 psi of balloons, is held for 15 seconds, then carries out additional pressure of the 15 more psi, holds it for 15 seconds, and it measures a pressure when it explodes as breaking strength repeatedly until a balloon explodes this step.

[0037]The disruptive strength of the balloon which carried out blow molding by the method mentioned above is shown in Table 1. The dose of the electron beam was prepared by 40Mrad and 60Mrad, and the disruptive strength of the balloon which carried out blow molding using what has a gel content in the same grade as the conventional bridge construction tube was shown in Table 1 as a comparative example. The result of Table 1 shows that as for the balloon for balloon catheters of this invention the thickness of a balloon has thin effective draw magnification in not less than 500%, and disruptive strength is increasing substantially.

[0038]

[Table 1]

	実 施 例					比較例	
	1	2	3	4	5	1	2
電子線照射量MR.	20	20	20	20	20	40	60
ゲル含量%	0.7	0.7	0.7	0.7	0.7	0.9	1.0
有効延伸倍率%	530	550	580	610	540	310	280
膜厚 μm	23	24	29	17	25	48	66
破壊応力 kgf/cm^2	1311	1213	1135	1614	1161	870	690

[0039]Next, the embodiment of the balloon catheter which uses the balloon for balloon catheters of this invention is described based on Drawings. The entire configuration figure of the balloon catheter which requires drawing 1 (A) for one embodiment of this invention, The sectional view which meets the IB-IB line which shows drawing 1 (A) drawing 1 (B), the sectional view which meets the IC-IC line which shows drawing 1 (A) drawing 1 (C), the sectional view which meets the ID-ID line which shows drawing 1 (A) drawing 1 (D), and drawing 1 (E) show the sectional view which meets the IE-IE line shown in drawing 1 (A). Drawing 2 shows important section drawing of longitudinal section of the balloon catheter shown in drawing 1 (A).

[0040]The balloon catheter 2 concerning this embodiment shown in drawing 1 is used for methods, such as an extended way of blood vessels, such as percutaneous transluminal coronary angioplasty (PTCA) and the limbs, an extended way of a top ureter, and a renal vasodilatation way, for example, and it is used in order to extend the narrow segment formed in a blood vessel or the other abdominal cavities. The following explanation explains as an example the case where the balloon catheter 2 of this embodiment is used for PTCA.

[0041]The balloon catheter 2 for extension of this embodiment is the so-called balloon catheter of a monorail method.

It has the balloon part 4, the outer tube 6 as a catheter tube, and the connector 8.

The outer tube 6 consists of the comparatively supple 1st outer tube member 6a and the 2nd outer tube member 6b with comparatively high rigidity joined to the 1st outer tube member 6a concerned by the joined part 9.

[0042]Penetrate the tube wall located in the middle of the longitudinal direction of the 1st outer tube member 6a, and the proximal edge opening of an inner tube carries out the opening of this embodiment outside, and The proximal edge opening of an inner tube, By adopting the structure where thermal melting arrival of the tube wall of the 1st outer tube member 6a has been carried out airtightly, only the distal end of a balloon catheter serves as the so-called catheter tube structure of coaxial structure.

[0043]As shown in drawing 1 (C), in this embodiment the cross section contour shape of the 2nd outer tube member 6b, The maximum sectional width x_m of the catheter tube of an X axial direction vertical to a Y-axis in the section of the outer tube member 6 which has elliptical [long and slender] in Y shaft orientations, a ratio (x_m/y_m) with the maximum sectional width y_m of Y shaft orientations is in the range of 0.8-0.1 — the 3rd of section semicircular shapes — lumen 24 and a round cross section — the 4th lumen, along said Y shaft orientations, 26 dissociates and is formed.

[0044]The 3rd lumen, the cross sectional area of the semicircular shapes of 24 should just be cross sectional area sufficient in order that the pressure fluid for balloon extension may circulate, and although it is not limited in particular, it is 0.08-0.20- mm^2 preferably. The 4th lumen, the circular cross sectional area of 26 should just be area sufficient since the reinforcing rod 28 is inserted in an inside, and although it is not limited in particular, it is 0.1-0.2- mm^2 preferably [it is desirable and] to 0.05-0.5- mm^2 and a pan.

[0045]As for the maximum sectional width y_m of Y shaft orientations, in this embodiment, about 0.6-1.2 mm is preferred in the section of the 2nd outer tube member 6b. Since the distal end of the 2nd outer tube member 6b

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is joined to the proximal edge of the 1st outer tube member 6a of a round cross section, the lateral cross sectional shape of the joined part 9 neighborhood. In order to make it in agreement with circular section shape with the 1st outer tube member 6a, it is considered as sectional shape which changes from an irregular shape cross to a circular section gradually towards the joined part 9.

[0046]the 3rd formed along with the longitudinal direction of this 2nd outer tube member 6b — lumen 24 — the 1st outer tube member 6a — the 1st lumen is open for free passage with 10, it lets these pass, and a fluid is taken in and out of the space for extension of the balloon part 4. It is a lumen for 26 to insert [of the 2nd outer tube 6b] the 4th lumen of the reinforcing rod 28.

the 1st outer tube member 6a — although 10 [lumen / 1st] is open for free passage, the proximal edge of this lumen 26 is closed in the portion of the connector 8, and receipts and payments of a fluid are not performed. The proximal end part of the 2nd outer tube member 6c is connected with the connector 8, and the port of the 2nd outer tube 6b which is open for free passage to 24 the 3rd lumen is formed in it. A port is a portion which goes a pressure fluid in and out.

The 4th lumen is open for free passage to 26.

[0047]the reinforcing rod 28 shown in drawing 1 (B), (C), and (F) — the 2nd outer tube member 6b — the overall length was covered and it was inserted in the inside of 26, and the distal end overcame the joined part 9 with the 1st outer tube member 6a, and the 4th lumen is sticking out of it in 1st lumen 10 of the 1st outer tube member 6a. The proximal end part of the reinforcing rod 28 is a round cross section.

It becomes thin to tapered shape towards the middle to the distal end side, and further, the sectional shape is changing gradually in the distal end so that it may grow into section flat plate shape.

As shown in drawing 1 (D) and drawing 2, the distal end of the section plate-like reinforcing rod 28 is the position which also overcame slightly (preferably about 1–10 cm) the proximal edge opening 22 of the inner tube 12, and is joined by thermal melting arrival, adhesion, or other means to the wall of the 1st outer tube member 6a.

[0048]Although the maximum outer diameter of the reinforcing rod 28 is determined possible [the 4th lumen of the insertion to the inside of 26] for the 2nd outer tube member 6b and is not limited in particular, it is 0.3–0.6 mm preferably.

[0049]The balloon part 4 shown in drawing 1 and drawing 2, comprises a tubed membrane by which the diameter of both ends was reduced, and 10–40 micrometers of the thickness is 15–35 micrometers preferably. As long as the balloon part 4 is cylindrical, it may not be limited in particular but a cylinder or the shape of a multiple cartridge may have as it. The outer diameter of the balloon part 4 at the time of extension is usually 3–7 mm preferably about 1.5–10.0 mm. Although the shaft-orientations length in particular of the balloon part 4 is not limited, it is 20–40 mm preferably 15–50 mm. The balloon part 4 before extending is folded up around the inner tube 12, and is twisted, and the outer diameter is small as much as possible.

[0050]having joined the proximal end part 5 of the balloon part 4 to the distal end periphery of the 1st outer tube member 6a by thermal melting arrival, adhesion, or other means, as shown in drawing 2, — the 1st outer tube member 6a — 10 [lumen / 1st] is open for free passage with the space for internal extension of the balloon part 4. The distal end 7 of the balloon part 4 is joined by thermal melting arrival, adhesion, or other means to the distal end periphery of the inner tube 14, and the space for internal extension of the balloon part 4 is sealed to the exterior except 1st lumen 10. It is a passage for [of the 1st outer tube member 6a] 10 sending the 1st lumen of a fluid into the internal growth space of the balloon part 4, and making the balloon part 4 extend, or sampling a fluid from the growth space of the balloon part 4, and shrinking the balloon part 4.

[0051]As shown in drawing 2, as for the growth space [of the balloon part 4], and distal end side of the 1st outer tube member 6a, the 1st lumen of the inner tube 12 is extended to shaft orientations in the shape of the same axle in the inside of 10, and has the so-called catheter tube structure of coaxial structure. The periphery of the inner tube 12 located in the inside of the balloon part 4 is equipped with the imaging ring 15, and when inserting the balloon catheter 2 in the living body, imaging is possible about the position of the imaging ring 15 through a living body's exterior to X-rays etc. Metal, such as gold, platinum, and tungsten, is illustrated as a material of the imaging ring 15.

[0052]14 [lumen / 2nd] is formed in the inside of the inner tube 12, and the opening of the distal end opening 20 is carried out to it in the distal end 7 of the balloon part 4. The proximal edge opening 22 of the inner tube 12 penetrates the breakthrough 21 of a tube wall located in the middle of the longitudinal direction of the 1st outer tube member 6a, and is carrying out the opening outside. The periphery of the proximal edge opening 22 of the inner tube 12 and the periphery of the breakthrough 21 of the tube wall of the 1st outer tube member 6a are airtightly joined by the thermal melting arrival method mentioned later. Although the shape in particular of the proximal edge opening 22 of the inner tube 12 is not limited but can take various shape, such as circular and an

ellipse form, as shown in drawing 5, it is elliptical [which cut the open end of the inner tube 12 aslant] in this embodiment. The 2nd lumen turns into a lumen for guidewire insertion which the guidewire 42 shown in drawing 2 for 14 to guide [of the inner tube 12] the balloon catheter 2 into the abdominal cavity inserts in.

[0053]Although the inner tube 12 can be constituted from soft synthetic resin of the same material as the 1st outer tube member 6a, a hard synthetic resin may constitute it from the 1st outer tube member 6a. As for the position, as for, the proximal edge opening 22 of the inner tube 12 carries out an opening to the outside of the 1st outer tube member 6a, it is preferred that it is a position of the distal end of the 1st outer tube member 6a to the length L1, and the length L1 is 200-300 mm still more preferably 150-350 mm preferably.

[0054]Although the outer diameter in particular of the 1st outer tube member 6a is not limited, it is 0.5-1 mm still more preferably 0.5-5 mm preferably. Although the thickness in particular of the 1st outer tube member 6a is not limited, it is 0.1-0.2 mm still more preferably 0.05-0.5 mm preferably.

[0055]Although the outer diameter of the inner tube 12 is determined that a crevice is formed and is not limited in particular between the 1st outer tube members 6a, it is 0.3-0.8 mm still more preferably 0.3-3 mm preferably. Especially if the inside diameter of the inner tube 12 is a path which can insert in the guidewire 42, it will not be limited, for example, it is 0.25-0.6 mm preferably 0.15-1.0 mm.

[0056]According to this embodiment, in order to reinforce the intensity of the 1st outer tube member 6a by the side of a proximal edge from the opening 22 neighborhood, as shown in drawing 2, the reinforcing rod 28 may be arranged from the opening 22 neighborhood inside the 1st outer tube member 6a by the side of a proximal edge. The proximal end part of this reinforcing rod 28 is a round cross section.

It becomes thin to tapered shape towards the middle to the distal end side, and further, the sectional shape is changing gradually in the distal end so that it may grow into section flat plate shape.

As shown in drawing 2, the distal end of the section plate-like reinforcing rod 28 is the position which overcame slightly (preferably about 1-10 cm) the proximal edge opening 22 of the inner tube 12, and is joined by thermal melting arrival, adhesion, or other means to the wall of the 1st outer tube member 6a.

[0057]The reinforcing rod 28 consists of synthetic resins, such as metallic materials, such as stainless steel, copper, a copper alloy, titanium, and a titanium alloy, or polyimide, polyamide, and polyethylene terephthalate. Although the maximum outer diameter of the reinforcing rod 28 is determined that it will not close the lumen 10 of the 1st outer tube member 6a and is not limited in particular, it is 0.3-0.6 mm preferably.

[0058]Although the 1st outer tube member 6a may comprise the same material as the balloon part 4, for example, it is preferred to comprise material which has flexibility. For example, polyethylene, polyethylene terephthalate, polypropylene, Ethylene propylene rubber, an ethylene-vinylacetate copolymer, polyvinyl chloride (PVC), The constructed type ethylene-vinylacetate copolymer of a bridge, polyurethane, polyamide, A polyamide elastomer, polyimide, a polyimide elastomer, polytetrafluoroethylene resin, Tetrafluoroethylene hexafluoride propylene copolymerization resin, tetrafluoroethylene perfluoroalkyl vinyl ether copolymerization resin, Ethylene chloride trifluoride resin, tetrafluoroethylene ethylene copolymerization resin, polyvinylidene fluoride resin, polyvinyl fluoride, silicone rubber, crude rubber, etc. are mentioned. Especially, polyethylene, polyamide, and polyimide are preferred. That whose JIS hardness is about 50A-90A can be used for the hardness of the 1st outer tube member 6a concerned.

[0059]The 2nd outer tube member 6b comprises the same material as said 1st outer tube member. That whose JIS hardness is about 50D-75D can be used for the hardness of the 2nd outer tube member 6b concerned.

[0060]It is preferred to have covered with this embodiment the covering material which comprises the hydrophilic polymer material which has lubricity in the periphery of the outer tube 6 which comprises the 1st outer tube member 6a and the 2nd outer tube member made of a fluoro-resin by a damp or wet condition.

[0061]

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DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]

[Drawing 1]The entire configuration figure of the balloon catheter which requires drawing 1 (A) for the embodiment of this invention, The sectional view which meets the IB-IB line which shows drawing 1 (A) drawing 1 (B), the sectional view which meets the IC-IC line which shows drawing 1 (A) drawing 1 (C), The sectional view which meets the ID-ID line which shows drawing 1 (A) drawing 1 (D), the sectional view which meets the IE-IE line which shows drawing 1 (A) drawing 1 (E), and drawing 1 (F) are the side views of the reinforcing rod inserted into the catheter tube of a balloon catheter.

[Drawing 2]Drawing 2 is important section drawing of longitudinal section of the balloon catheter shown in drawing 1 (A).

[Drawing 3]An important section sectional view when drawing 3 (A) fixes parison to a blow molding machine, and drawing 3 (b) are the perspective views of the balloon obtained by blow molding.

[Description of Notations]

- 2 -- Balloon catheter
- 4 -- Balloon part
- 6 -- Outer tube
- 6a -- The 1st outer tube member
- 6b -- The 2nd outer tube member
- 8 -- Connector
- 10 -- The 1st lumen
- 12 -- Inner tube
- 14 -- The 2nd lumen
- 20 -- Distal end opening
- 21 -- Breakthrough
- 22 -- Proximal edge opening
- 24 -- The 3rd lumen
- 26 -- The 4th lumen
- 28 -- Reinforcing rod
- 28a -- Reinforcing member
- 54, 56, 60 -- Mandrel
- 7a -- Parison
- 7b -- Top zipper
- 7c -- Lower zipper
- 7d -- Heating heater
- 7e -- Balloon body
- 7f -- Joined part with the main part of a balloon catheter

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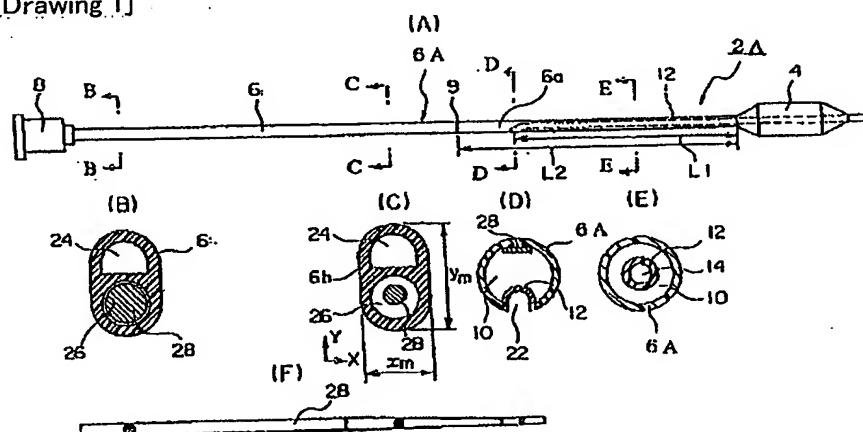
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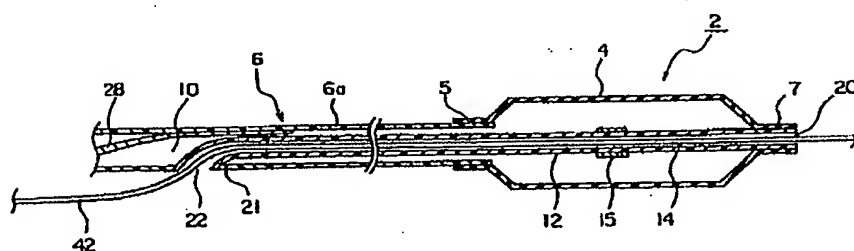
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DRAWINGS

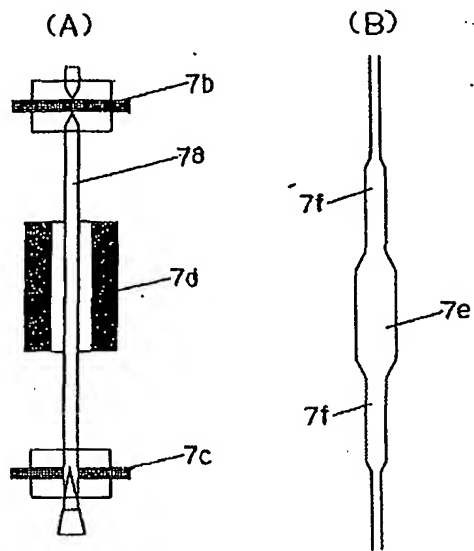
[Drawing 1]



[Drawing 2]



[Drawing 3]



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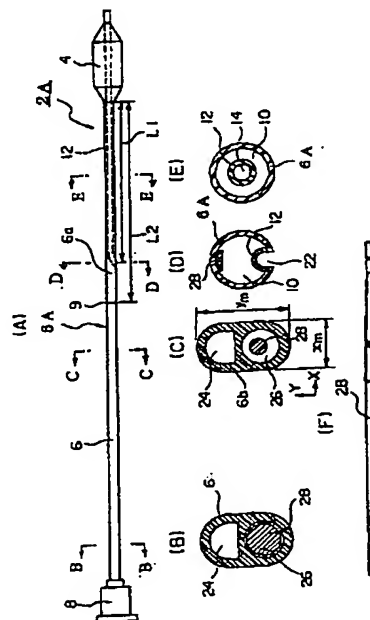
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(54) 【発明の名称】 バルーンカテーテル用バルーンおよびその製造方法

(57) 【要約】

【課題】 肉薄かつ高強度なバルーンを有する、PTC
A用途に好適なバルーンカテーテルを提供すること。

【解決手段】 少なくとも一つのバルーン拡張用ルーメ
ンが長手方向に沿って形成してある外チューブと、前記
外チューブの遠位端部にバルーン部の近位端部が接合さ
れ、前記バルーン拡張用ルーメンと内部が連通するバル
ーン部と、前記バルーン部の内部に密閉された拡張用空
間を形成するように、バルーン部の遠位端部が内チュ
ーブの遠位端部に接合され、前記バルーン部の内部と前記
外チューブのバルーン拡張用ルーメンの内部とに軸方向
に延在する内チューブとを有し、前記バルーンが、結晶
性ポリオレフィン系樹脂からなる架橋チューブを用いて
ブロー成形されたものであり、前記バルーンの膜厚が1
0~40 μm であり、前記バルーンの破断強度が800
~2000 kgf/cm^2 であることを特徴とするバ
ルーンカテーテル。



【特許請求の範囲】

【請求項1】 ポリオレフィン系樹脂からなる架橋チューブを用いてブロー成形により成形されたバルーンであって、前記バルーンの膜厚が $10 \sim 40 \mu\text{m}$ であり、前記バルーンの破断強度が $800 \sim 2000 \text{ kgf/cm}^2$ であることを特徴とするバルーンカテーテル用バルーン。

【請求項2】 ポリオレフィン系樹脂からなるチューブを電子線架橋して、
 ゲル含量が0.2～0.8%である架橋チューブを調製する工程と、
 前記ポリオレフィン系樹脂の融点よりも 10°C 以上低い温度で、前記架橋チューブに1次ブロー圧を負荷し、次いで、前記架橋チューブに前記1次ブロー圧よりも低い圧力である2次ブロー圧を負荷することにより該架橋チューブからバルーンに至る有効延伸倍率が $500 \sim 1000\%$ となるように、ブロー成形してバルーン部を調製する工程とを有する、請求項1に記載したバルーンカテーテル用バルーンの製造方法。

【請求項3】 少なくとも一つのバルーン拡張用ルーメンが長手方向に沿って形成してある外チューブと、前記外チューブの遠位端部にバルーン部の近位端部が接合され、前記バルーン拡張用ルーメンと内部が連通するバルーン部と、
 前記バルーン部の内部に密閉された拡張用空間を形成するように、バルーン部の遠位端部が内チューブの遠位端部に接合され、前記バルーン部の内部と前記外チューブのバルーン拡張用ルーメンの内部とに軸方向に延在する内チューブとを有し、
 前記バルーン部が、ポリオレフィン系樹脂からなる架橋チューブを用いてブロー成形により成形されたバルーンであって、前記バルーンの膜厚が $10 \sim 40 \mu\text{m}$ であり、前記バルーンの破断強度が $800 \sim 2000 \text{ kgf/cm}^2$ であることを特徴とするバルーンカテーテル。

【発明の詳細な説明】

【0001】

【発明の属する技術分野】 本発明は、肉薄かつ高強度なバルーンを有するバルーンカテーテルに関し、詳しくは、経皮的血管内冠動脈形成術（Percutaneous Transluminal Coronary Angioplasty、以下、「PTCA」と記す。）用途に好適なバルーンカテーテルに関する。

【0002】

【従来の技術】 血管の狭窄に由来する疾病には、バルーンカテーテルによって、簡便に処置、回復させるいわゆるPTCAカテーテルが頻繁に用いられている。

【0003】 PTCAカテーテルは、例えば、心臓の冠動脈の処置では、まず冠動脈入り口までガイドワイヤが挿入され、次に、ガイドワイヤが狭窄

部を超えて挿入され、そして、バルーンカテーテルが狭窄部まで押し込まれ、バルーンを拡張することにより狭窄部を拡張するものである。

【0004】 PTCAカテーテルは、その利点を生かして、適用範囲の拡大が図られているが、それにつれて要求特性も高度化している。例えば、末梢の冠動脈狭窄の処置ができること、屈曲血管への挿入が容易であること、強い拡張圧力を有すること、安全に血管拡張ができることなどが要求されている。より具体的には、PTCAカテーテルを用いて、従来よりも末梢の冠動脈狭窄の処置ができることが求められている。そのためには、従来以上に肉薄でかつ高強度のバルーンが求められている。

【0005】 しかし、従来より、PTCAカテーテルのバルーン用材料として、主として用いられているポリエチレン系樹脂（例えば、特開平8-196620号公報等）の場合は、一般に電子線を照射して、そのゲル分率が0.9%程度になるまで架橋させることによって、バルーン材料としての延伸特性の向上・破断圧の向上などを図る手法が採用されている。

【0006】 この場合は、架橋されたポリエチレン系樹脂には0.9%程度のゲルが生成していることから、バルーンの膨張は300%程度に留まり、また、その厚さが薄くなるほどバルーンの強度は低下し、破断に至る圧力も低下するために、肉薄で高強度のバルーンを得るには限界があった。

【0007】

【発明が解決しようとする課題】 本発明の目的は、肉薄かつ高強度な、PTCA用途に好適なバルーンカテーテル用バルーンを提供することを目的とする。また、本発明の目的は、前記肉薄かつ高強度なポリオレフィン系樹脂製バルーンの製造方法を提供することを目的とする。さらに、本発明の目的は、前記肉薄かつ高強度なポリオレフィン系樹脂製バルーンを有するバルーンカテーテルを提供することを目的とする。

【0008】 そこで、本発明者らは鋭意研究した結果、ポリエチレン樹脂製チューブに、ゲル分率が0.7%程度のゲルが生成するように電子線照射を施して架橋し、続いて該架橋チューブを、前記ポリエチレン系樹脂の融点よりもかなり低温である 80°C の条件でブロー成形したところ、延伸倍率が 600% かつ破断強度が 1100 kgf/cm^2 であるバルーンが得られることを見出し、この知見に基づき本発明を完成するに至った。

【0009】

【課題を解決するための手段】 かくして本発明によれば、下記（1）、（2）及び（3）が提供される。

（1）ポリオレフィン系樹脂からなる架橋チューブを用いてブロー成形により成形されたバルーンであって、前記バルーンの膜厚が $10 \sim 40 \mu\text{m}$ であり、前記バルーンの破断強度が $800 \sim 2000 \text{ kgf/cm}^2$ であ

ることを特徴とするバルーンカテーテル用バルーン。

【0010】(2) ポリオレフィン系樹脂からなるチューブを電子線架橋して、ゲル含量が0.2～0.8%である架橋チューブを調製する工程と、前記結晶性ポリオレフィン系樹脂の融点よりも10℃以上低い温度で、前記架橋チューブに1次ブロー圧を負荷し、次いで、前記架橋チューブに前記1次ブロー圧よりも低い圧力である2次ブロー圧を負荷することにより該架橋チューブからバルーンに至る有効延伸倍率が500～1000%となるように、ブロー成形してバルーン部を調製する工程とを有する、前記(1)に記載したバルーンカテーテル用バルーンの製造方法。

【0011】(3) 少なくとも一つのバルーン拡張用ルーメンが長手方向に沿って形成してある外チューブと、前記外チューブの遠位端部にバルーン部の近位端部が接合され、前記バルーン拡張用ルーメンと内部が連通するバルーン部と、前記バルーン部の内部に密閉された拡張用空間を形成するように、バルーン部の遠位端部が内チューブの遠位端部に接合され、前記バルーン部の内部と前記外チューブのバルーン拡張用ルーメンの内部とに軸方向に延在する内チューブとを有し、前記バルーン部が、ポリオレフィン系樹脂からなる架橋チューブを用いてブロー成形により形成されたバルーンであって、前記バルーンの膜厚が10～40μmであり、前記バルーンの破断強度が800～2000kgf/cm²であることを特徴とするバルーンカテーテル。

【0012】本発明のバルーンカテーテル用バルーンの製造方法において、ポリオレフィン系樹脂からなるチューブに5～40Mrad、好ましくは10～20Mradの電子線を照射して、前記チューブを電子線架橋して、ゲル含量が0.2～0.7%である架橋チューブとすることが好ましい。さらに、当該架橋チューブを、少なくとも90℃で熱処理することが好ましい。

【0013】前記バルーンの製造方法において、前記架橋チューブをブロー成形する場合は、金型に1次ブロー圧を15～25kgf/cm²を負荷し、かつ、金型を開く少なくとも1秒前に、5～8kgf/cm²の2次ブロー圧を負荷してバルーンを作成することが好ましい。

【0014】本発明において、ポリオレフィン系樹脂からなるバルーンカテーテル用バルーンの膜厚は、25～35μmであることが好ましい。

【0015】本発明において、ポリオレフィン系樹脂からなるバルーンカテーテル用バルーンは、前記架橋チューブからバルーンに至る有効延伸倍率が、500～700%であることが好ましい。さらに、前記バルーンの破断強度が、1000～2000kgf/cm²であることが好ましい。

【0016】

【作用】本発明のバルーンカテーテル用バルーンは、通

常、ポリエチレン樹脂をブロー成形して得られるバルーンと比較して、バルーンの破壊強度が極めて高いことから、バルーン拡張のための高圧力に耐えることができ、例えばPTCAバルーンカテーテルとして使用した場合は、血管狭窄部分を拡張する際の安全性が極めて優れている。

【0017】また、本発明のバルーンカテーテル用バルーンは、その膜厚を非常に薄くすることができるので、例えば、PTCAカテーテルのバルーンとして使用する場合、PTCAカテーテルを細径化することができ、従来よりも末梢の冠動脈狭窄の処置が可能となる。

【0018】

【発明の実施の形態】本発明のバルーンカテーテル用バルーンは、ポリオレフィン系樹脂を用いて調製されたものである。前記ポリオレフィン系樹脂は、炭素数2～40のオレフィンをモノマーとして使用して、重合反応により製造したものであって、その密度(JIS K-7112)は、通常0.950g/cm³以下であり、好ましくは0.850～0.940g/cm³、より好ましくは0.880～0.930g/cm³である。密度が小さすぎるとバルーン表面のベタつきによるブロッキングなどの不都合を生じやすくなり、大きすぎると透明性が低下するので好ましくない。

【0019】重合反応によりポリオレフィン系樹脂を得るためのオレフィンのモノマーとしては、エチレン、プロピレン、1-ブテン、1-ペンテン、1-ヘキセン、1-オクテン、1-ヘプテン、4-メチル-1-ペンテン、4-メチル-1-ヘキセン、4,4-ジメチル-1-ペンテン等が挙げられる。これらのモノマーは、それぞれ単独で、あるいは2種以上を組み合わせて使用することができる。

【0020】ポリオレフィン系樹脂としては、バルーンとしての諸特性の観点から、ポリエチレン及びエチレン・α-オレフィン共重合体が好ましく、エチレン・α-オレフィン共重合体が特に好ましい。エチレン・α-オレフィン共重合体は、メタロセン触媒を用いてエチレンとα-オレフィンとを共重合することにより得ることができる。コモノマーとしては、炭素原子数4～40のα-オレフィンを使用することが好ましい。

【0021】前記α-オレフィンとしては、例えば、1-ブテン、1-ペンテン、1-ヘキセン、1-オクテン、1-ヘプテン、4-メチル-1-ペンテン、4-メチル-1-ヘキセン、4,4-ジメチル-1-ペンテンなどが挙げられる。これらの中でも、炭素原子数が4～12のα-オレフィンが好ましく、炭素原子数が4～10のα-オレフィンがより好ましい。α-オレフィンの共重合割合は、通常2～50重量%、好ましくは5～40重量%、より好ましくは10～30重量%である。

【0022】前記ポリオレフィン系樹脂の具体例としては、例えば、ポリエチレン樹脂、ポリプロピレン樹脂、

エチレン-プロピレン共重合樹脂、エチレンと他の α -オレフィンとの共重合樹脂等が挙げられる。なかでもポリエチレン樹脂が好ましく、低密度ポリエチレン、直鎖状低密度ポリエチレン、高密度ポリエチレン等を用いることが好ましい。

【0023】前記ポリオレフィン系樹脂のメルトフローレート(MFR; JIS K-7210)は、通常0.1~30.0g/10分、好ましくは1.0~20.0g/10分、より好ましくは1.0~15.0g/10分、最も好ましくは1.5~15.0g/10分である。MFRが小さすぎると十分な強度を得ることが困難であり、大きすぎると成型性が低下する。

【0024】本発明では、ポリオレフィン系樹脂に、本発明の目的を損なわない範囲内において、各種添加剤を配合することができる。添加剤としては、例えば、酸化防止剤、紫外線吸収剤、帯電防止剤、難燃剤、金属不活性化剤、顔料、染料、結晶核剤等を必要に応じて数種類添加することができる。この場合、要求する性質によるが、添加量は、ポリオレフィン系樹脂100重量部に対して、通常20重量部以下、好ましくは5重量部以下である。

【0025】本発明のバルーンカテーテル用バルーンの製造方法について説明する。まず、結晶性ポリオレフィン系樹脂を用いて、予め設計された寸法のブロー成形用元チューブを成形する。成形は、例えば押し出し成形法で行うことができ、押し出し時のダイ温度は、例えば200~300℃である。ダイから吐出直後の押し出しチューブは、例えば水槽(20~30℃)中を通過させて冷却される。

【0026】次に、前記押し出しチューブに電子線を照射し、ポリオレフィン系樹脂製架橋チューブ(以下、「パリソン」と記す。)を形成する。電子線の照射量は、例えば5~40Mrad、好ましくは10~20Mradである。その後、前記架橋チューブは、例えば90~110℃程度で、30分~数時間、熱処理が行われる。この熱処理工程により、押し出し成形による成形ひずみが解消される。

【0027】前記電子線照射により、架橋されたチューブのゲル分率は、0.8%以下、好ましくは、0.2~0.7%程度とすることが好ましい。ゲル分率は、架橋サンプルの加熱したキシレン中での不溶解分として測定することができる。具体的には、0.1gの架橋サンプルを120℃に加熱したキシレン100ml中で6時間加熱した後、可溶分を濾別し、残された架橋サンプルの乾燥重量を測定し、処理前の架橋サンプルに対する割合を算出する。

【0028】上記の工程を経て調製されたパリソンは、例えば、下記の工程を経て、ブロー成形によりバルーン状に賦形される。まず、図3(A)のように、パリソンの上下を固定する。上部チャックでは完全に圧力が漏れ

ないように封止し、下部チャックはブロー圧が加えられるようにルーメンはつぶさないようにする。

【0029】次に、前記パリソンは、パリソン材料の結晶性ポリオレフィン系樹脂の融点より低い温度でブロー成形される。前記温度は、例えば、結晶性ポリオレフィン樹脂の融点よりも、少なくとも10℃以上、好ましくは、30℃以上低温側の温度であり、さらに好ましくは30~60℃程度低温側の範囲である。前記温度が過度に高温の場合、ブロー成形は容易になるが、バルーンの破壊強度は低下する。一方過度に低温では、バルーンを賦形するためには、非常に高圧なブロー圧が必要となり好ましくない。また、低温側でブロー成形したバルーンは、極端に収縮が起きるので好ましくない。

【0030】ブロー成形は、具体的には、次の工程による。上下を固定されたパリソンは、本実施形態では、例えば、予め50~90℃前後で、好ましくは75~85℃の範囲で、30180分間、好ましくは100~150分間加熱された後、上下方向に150~200%程度延伸される。次に、パリソンが延伸されたのと同時に、両側から2つ割りにされた金型(パリソンと同程度に加熱してある)がパリソンを挟むように閉まり、続いて、第1ブロー圧力が負荷され、10~60秒間、好ましくは20~40秒間程度保持される。次に、第1ブロー圧力の少なくとも2分の1以下好ましくは3分の1以下のブロー圧力(以下、「第2ブロー圧力」と記す。)で0.5~3秒間保持され、その後、金型が開けられる。

【0031】パリソン中に導入される気体は、とくに限定されないが、例えば、窒素ガス等を使用することができる。パリソンを膨張させるための第1ブロー圧力は、例えば10~30kgf/cm²、好ましくは15~25kgf/cm²である。第2ブロー圧力は、例えば、3~10kgf/cm²、好ましくは5~8kgf/cm²である。

【0032】上述したブロー成形により、バルーンは、例えば図3(B)に示すように、バルーン本体部分7eとバルーンカテーテルと接合するための部分7fを有する形状に成形される。

【0033】ブロー成形により成形されたバルーンの外径は、レーザー外径測定器によって、1atmまたは6atmの圧力を加えたときの外径を測定する。バルーンの膜厚は、マイクロゲージにより測定する。

【0034】ブロー成形により成形されたバルーンの、架橋チューブからバルーンに至る有効延伸倍率(架橋チューブ断面積/バルーン断面積)は、400~1500%、好ましくは、500~1000%であることが必要である。有効延伸倍率が過度に大きい場合は、バルーンの破壊強度が極端に低下するので好ましくない。本発明においては、前記押し出しチューブを、5~40Mradの条件で電子線を照射し、ポリエチレン製架橋チューブを形成することにより、前記有効延伸倍率を400~

1500%で、かつ、前記バルーンの破断強度が800~2000kgf/cm²、好ましくは、1000~1800kgf/cm²であることが達成される。

【0035】本発明においては、前記ブロー成形により成形されたバルーンの膜厚は、5~40μm、好ましくは、25~35μmである。

【0036】バルーンの破断強度は、37℃の水中において、バルーンに15psi加圧して15秒間保持し、続いて、更に15psiを追加圧して15秒間保持し、このステップを、バルーンが破裂するまで繰り返し、破

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*【0037】上述した方法でブロー成形したバルーンの破壊強度を表1に示す。なお、電子線の照射量を、40Mrad、及び60Mradで調製し、ゲル含量を従来の架橋チューブと同じ程度に有するものを用いてブロー成形したバルーンの破壊強度を、比較例として表1に示した。表1の結果から、本発明のバルーンカテーテル用バルーンは、有効延伸倍率が500%以上において、バルーンの膜厚が薄く、かつ破壊強度が大幅に増大していることがわかる。

【0038】

* 【表1】

	実施例					比較例	
	1	2	3	4	5	1	2
電子線照射量MR.	20	20	20	20	20	40	60
ゲル含量%	0.7	0.7	0.7	0.7	0.7	0.9	1.0
有効延伸倍率%	530	550	580	610	540	310	280
膜厚μm	23	24	29	17	25	48	66
破壊応力kgf/cm ²	1311	1213	1135	1614	1161	870	690

【0039】次に、本発明のバルーンカテーテル用バルーンを使用したバルーンカテーテルの実施形態を、図面にに基づき説明する。図1(A)は本発明の1実施形態に係るバルーンカテーテルの全体構成図、図1(B)は図1(A)に示すI B-I B線に沿う断面図、図1(C)は図1(A)に示すI C-I C線に沿う断面図、図1(D)は図1(A)に示すI D-I D線に沿う断面図、図1(E)は図1(A)に示すI E-I E線に沿う断面図を示す。図2は図1(A)に示すバルーンカテーテルの要部縦断面図を示す。

【0040】図1に示す本実施形態に係るバルーンカテーテル2は、例えば経皮的冠動脈形成術(PTCA)、四肢等の血管の拡張術、上部尿管の拡張術、腎血管拡張術などの方法に用いられ、血管あるいはその他の体腔に形成された狭窄部を拡張するために用いられる。以下の説明では、本実施形態のバルーンカテーテル2をPTCAに用いる場合を例として説明する。

【0041】本実施形態の拡張用バルーンカテーテル2は、いわゆるモノレール方式のバルーンカテーテルであり、バルーン部4と、カテーテルチューブとしての外チューブ6と、コネクタ8とを有する。外チューブ6は、比較的柔軟性のある第1外チューブ部材6aと、当該第1外チューブ部材6aに接合部9にて接合される比較的剛性が高い第2外チューブ部材6bとで構成してある。

【0042】本実施形態は、内チューブの近位端開口部が、第1外チューブ部材6aの長手方向の途中に位置するチューブ壁を貫通して外部に開口し、内チューブの近位端開口部と、第1外チューブ部材6aのチューブ壁と

が気密に熱融着してある構造を採用することにより、バルーンカテーテルの遠位端部のみが、いわゆる同軸構造のカテーテルチューブ構造となるものである。

【0043】本実施形態では、図1(C)に示すように、第2外チューブ部材6bの横断面外形形状は、Y軸方向に細長い楕円形状を有し、外チューブ部材6の断面で、Y軸と垂直なX軸方向のカテーテルチューブの最大断面幅xmと、Y軸方向の最大断面幅ymとの比(xm/ym)が、0.8~0.1の範囲にあり、断面半円形の第3ルーメン24および断面円形の第4ルーメン26が、前記Y軸方向に沿って分離して形成してある。

【0044】第3ルーメン24の半円形の横断面積は、バルーン拡張用圧力流体が流通するために十分な横断面積であれば良く、特に限定されないが、好ましくは0.08~0.20mm²である。また、第4ルーメン26の円形の横断面積は、内部に補強ロッド28が挿入されるために十分な面積であれば良く、特に限定されないが、好ましくは0.05~0.5mm²、さらに好ましくは0.1~0.2mm²である。

【0045】本実施形態では、第2外チューブ部材6bの断面において、Y軸方向の最大断面幅ymは、0.6~1.2mm程度が好ましい。第2外チューブ部材6bの遠位端は、断面円形の第1外チューブ部材6aの近位端に対して接合されるため、その接合部9付近の横断面形状は、第1外チューブ部材6aとの円形断面形状と一致させるために、接合部9に向けて、異形断面から円形断面に徐々に変化するような断面形状とする。

【0046】この第2外チューブ部材6bの長手方向に

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沿って形成された第3ルーメン24は、第1外チューブ部材6aの第1ルーメン10と連通し、これらを通して、バルーン部4の拡張空間に流体の出し入れを行う。第2外チューブ6bの第4ルーメン26は、補強ロッド28を挿入するためのルーメンであり、第1外チューブ部材6aの第1ルーメン10とも連通するが、このルーメン26の近位端は、コネクタ8の部分で閉じられており、流体の出入りは行わない。コネクタ8には、第2外チューブ部材6cの近位端部が連結され、第2外チューブ6bの第3ルーメン24に対して連通するポートが形成してある。ポートは、圧力流体の出入りを行う部分であり、第4ルーメン26には連通しないようになっている。

【0047】図1(B)、(C)および(F)に示す補強ロッド28は、第2外チューブ部材6bの第4ルーメン26の内部に、全長に亘り挿入され、その遠位端部は、第1外チューブ部材6aとの接合部9を乗り越えて、第1外チューブ部材6aの第1ルーメン10内に飛び出している。補強ロッド28の近位端部は、断面円形であり、途中から遠位端側に向けてテーパ状に細くなり、さらに遠位端部では、断面平板形状に成るように、その断面形状が徐々に変化している。断面平板状の補強ロッド28の遠位端部は、図1(D)および図2に示すように、内チューブ12の近位端開口部22をも僅かに(好ましくは1~10cm程度)乗り越えた位置で、第1外チューブ部材6aの内壁に対して熱融着または接着などの手段で接合してある。

【0048】なお、補強ロッド28の最大外径は、第2外チューブ部材6bの第4ルーメン26の内部に挿入可能に決定され、特に限定されないが、好ましくは0.3~0.6mmである。

【0049】図1および図2に示すバルーン部4は、両端部が縮径された筒状の膜体で構成され、その膜厚は、10~40 μ m、好ましくは15~35 μ mである。バルーン部4は、筒状であれば、特に限定されず、円筒または多角筒形状でも良い。また、拡張時のバルーン部4の外径は、通常1.5~10.0mm程度、好ましくは、3~7mmである。バルーン部4の軸方向長さは、特に限定されないが、15~50mm、好ましくは20~40mmである。拡張する前のバルーン部4は、内チューブ12の周囲に折り畳まれて巻き付けられ、可能な限り外径が小さくなっている。

【0050】図2に示すように、第1外チューブ部材6aの遠位端部外周には、バルーン部4の近位端部5が熱融着または接着などの手段で接合してあり、第1外チューブ部材6aの第1ルーメン10がバルーン部4の内部拡張空間と連通するようになっている。バルーン部4の遠位端部7は、内チューブ14の遠位端部外周に対して熱融着または接着などの手段で接合してあり、バルーン部4の内部拡張空間は、第1ルーメン10以外で

は、外部に対して密封してある。第1外チューブ部材6aの第1ルーメン10は、バルーン部4の内部拡張空間に流体を送り込み、バルーン部4を拡張させたり、流体をバルーン部4の拡張空間から抜き取りバルーン部4を収縮させたりするための通路である。

【0051】図2に示すように、内チューブ12は、バルーン部4の拡張空間および第1外チューブ部材6aの遠位端側第1ルーメン10の内部を同軸状に軸方向に伸び、いわゆる同軸構造のカテーテルチューブ構造となっている。バルーン部4の内部に位置する内チューブ12の外周には、造影リング15が装着してあり、バルーンカテーテル2を生体内に挿入する際に、生体の外部からX線などで造影リング15の位置を造影が可能になっている。造影リング15の材料としては、金、白金、タングステンなどの金属が例示される。

【0052】内チューブ12の内部には、第2ルーメン14が形成してあり、その遠位端開口部20は、バルーン部4の遠位端部7で開口している。内チューブ12の近位端開口部22は、第1外チューブ部材6aの長手方向の途中に位置するチューブ壁の貫通孔21を貫通して外部に開口している。内チューブ12の近位端開口部22の周縁と、第1外チューブ部材6aのチューブ壁の貫通孔21の周縁とは、後述する熱融着方法により気密に接合してある。内チューブ12の近位端開口部22の形状は、特に限定されず、円形、楕円形など種々の形状を採り得るが、本実施形態では、図5に示すように、内チューブ12の開口端部を斜めに切断した楕円形状である。内チューブ12の第2ルーメン14は、バルーンカテーテル2を体腔内に案内するための図2に示すガイドワイヤ42が挿通するガイドワイヤ挿入用ルーメンとなる。

【0053】内チューブ12は、第1外チューブ部材6aと同様な材料の軟質合成樹脂で構成することができるが、第1外チューブ部材6aよりも硬質の合成樹脂で構成しても良い。内チューブ12の近位端開口部22が第1外チューブ部材6aの外側に開口する位置は、第1外チューブ部材6aの遠位端から長さL1の位置であることが好ましく、長さL1は、好ましくは150~350mm、さらに好ましくは200~300mmである。

【0054】第1外チューブ部材6aの外径は、特に限定されないが、好ましくは0.5~5mm、さらに好ましくは0.5~1mmである。第1外チューブ部材6aの肉厚は、特に限定されないが、好ましくは0.05~0.5mm、さらに好ましくは0.1~0.2mmである。

【0055】内チューブ12の外径は、第1外チューブ部材6aとの間に隙間が形成されるように決定され、特に限定されないが、好ましくは0.3~3mm、さらに好ましくは0.3~0.8mmである。内チューブ12の内径は、ガイドワイヤ42を挿通できる径であれば特

に限定されず、例えば0.15～1.0mm、好ましくは0.25～0.6mmである。

【0056】本実施形態では、開口部22付近から近位端側の第1外チューブ部材6aの強度を補強するために、図2に示すように、補強ロッド28を、開口部22付近から近位端側の第1外チューブ部材6aの内部に配置しても良い。この補強ロッド28の近位端部は、断面円形であり、途中から遠位端側に向けてテーパ状に細くなり、さらに遠位端部では、断面平板形状に成るように、その断面形状が徐々に変化している。断面平板状の補強ロッド28の遠位端部は、図2に示すように、内チューブ12の近位端開口部22を僅かに（好ましくは1～10cm程度）乗り越えた位置で、第1外チューブ部材6aの内壁に対して熱融着または接着などの手段で接合してある。

【0057】なお、補強ロッド28は、ステンレス鋼、銅、銅合金、チタン、チタン合金などの金属材料、あるいはポリイミド、ポリアミド、ポリエチレンテレフタレートなどの合成樹脂で構成してある。補強ロッド28の最大外径は、第1外チューブ部材6aのルーメン10を塞がないように決定され、特に限定されないが、好ましくは0.3～0.6mmである。

【0058】第1外チューブ部材6aは、例えばバルーン部4と同様な材料で構成されて良いが、可撓性を有する材料で構成されることが好ましい。例えば、ポリエチレン、ポリエチレンテレフタレート、ポリプロピレン、エチレン-プロピレン共重合体、エチレン-酢酸ビニル共重合体、ポリ塩化ビニル（PVC）、架橋型エチレン-酢酸ビニル共重合体、ポリウレタン、ポリアミド、ポリアミドエラストマー、ポリイミド、ポリイミドエラストマー、ポリ四フッ化エチレン樹脂、四フッ化エチレン-六フッ化プロピレン共重合樹脂、四フッ化エチレン-パーフルオロアルキルビニルエーテル共重合樹脂、三フッ化塩化エチレン樹脂、四フッ化エチレン-エチレン共重合樹脂、ポリフッ化ビニリデン樹脂、ポリフッ化ビニル樹脂、シリコーンゴム、天然ゴム等が挙げられる。なかでも、ポリエチレン、ポリアミド、ポリイミドが好ましい。また、当該第1外チューブ部材6aの硬さは、JIS硬度が50A～90A程度のものを用いることができる。

【0059】第2外チューブ部材6bは、前記第1外チューブ部材と同様な材料で構成される。当該第2外チューブ部材6bの硬さは、JIS硬度が50D～75D程度のものを用いることができる。

【0060】なお、本実施形態では、第1外チューブ部材6a及びフッ素樹脂製第2外チューブ部材とから成る外チューブ6の外周には、湿润状態で潤滑性を持つ親水性高分子物質から成る被覆材が被覆してあることが好ましい。

【0061】

【発明の効果】かくして本発明によれば、バルーンの膜厚が薄く、かつ、その破壊強度が大幅に向上したバルーンカテーテル用バルーンが提供される。本発明のバルーンカテーテル用バルーンは、通常、結晶性ポリエチレン樹脂の融点近傍（110℃）でブロー成形して得られるバルーンと比較して、バルーンの膜厚が薄く、その破壊強度が高いことから、バルーンカテーテルを細径化し、さらに、バルーン拡張のための高圧力に耐えることができ、例えばPTCAバルーンカテーテルとして使用した場合は、血管狭窄部分を拡張する際の安全性が極めて優れている。

【図面の簡単な説明】

【図1】 図1(A)は、本発明の実施形態に係るバルーンカテーテルの全体構成図、図1(B)は図1(A)に示すIB-IB線に沿う断面図、図1(C)は図1(A)に示すIC-IC線に沿う断面図、図1(D)は図1(A)に示すID-ID線に沿う断面図、図1(E)は図1(A)に示すIE-IE線に沿う断面図、図1(F)はバルーンカテーテルのカテーテルチューブ内に挿入される補強ロッドの側面図である。

【図2】 図2は図1(A)に示すバルーンカテーテルの要部縦断面図である。

【図3】 図3(A)は、ブロー成形機にパリソンを固定したときの要部断面図、図3(b)は、ブロー成形により得られたバルーンの斜視図である。

【符号の説明】

- 2… バルーンカテーテル
- 4… バルーン部
- 6… 外チューブ
- 6a… 第1外チューブ部材
- 6b… 第2外チューブ部材
- 8… コネクタ
- 10… 第1ルーメン
- 12… 内チューブ
- 14… 第2ルーメン
- 20… 遠位端開口部
- 21… 貫通孔
- 22… 近位端開口部
- 24… 第3ルーメン
- 26… 第4ルーメン
- 28… 補強ロッド
- 28a… 補強部材
- 54, 56, 60… マンドレル
- 7a… パリソン
- 7b… 上部チャック
- 7c… 下部チャック
- 7d… 加熱ヒーター
- 7e… バルーン本体
- 7f… バルーンカテーテル本体との接合部

Fig. 1 consists of two schematic diagrams, (A) and (B), illustrating the apparatus. Diagram (A) is a top-down view showing a central vertical tube (7a) passing through a rectangular block (7b) at the top and another rectangular block (7c) at the bottom. The tube (7a) is surrounded by a textured material (7d) in the middle section. Diagram (B) is a side view showing a vertical tube (7e) with two flared sections (7f) at the top and bottom, connected by a narrower central section.